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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,516	08/20/2003	Steven K. MacLeod	PC27664A	5971

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GLOBAL PATENT DEPARTMENT
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EXAMINER

DEAK, LESLIE R

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/644,516	Applicant(s) MACLEOD, STEVEN K.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,089,432 to Crankshaw et al in view of US 5,549,561 to Hjertman.

In the specification and figures, Crankshaw discloses the invention substantially as claimed by applicant. With regard to claims 1-3,

In particular, Crankshaw discloses the structure of a vial 11 with two chambers 13, 14 a stopper 17 intermediate the chambers, and an upper stopper 23. Crankshaw discloses that movement of the upper stopper is an actuating means that pushes the intermediate stopper out of its seal with the constricted portion 16 of the vial, allowing the contents of the two chambers to mix within the combined volume of the two chambers. Crankshaw further discloses the cap 44 over the top of the stopper, a thin wall of the stopper for needle piercing, and the connections, sleeves, and locks of the claimed vial (see, generally, columns 2-4).

Crankshaw fails to disclose that the upper chamber is filled with an aqueous suspension and the lower chamber is filled with a gaseous medium. Crankshaw does teach, however, that the purpose of the two-compartment vial is to provide a stable storage solution wherein two substances, which may include a medication, may be

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stored completely independently from one another. Such independent storage is used when the combination of the substances in the first and second vials reduces the stability and shelf life of the combined solution or medicine. Hjertman discloses a medicament vial with a first and second chamber 6, 7, separated by barrier 8, and a third chamber 15 filled with a gaseous medium, separated by barrier 13. During operation, the compartments 6 and 7 are combined, creating a single chamber with an aqueous suspension therein, separated from gaseous chamber 15 by barrier 13 (see FIG 2, column 5). This arrangement allows for the storage of incompatible components in a single vial while providing sufficient headspace in chamber 15 to mix the medicament prior to patient administration (see column 6, lines 20-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the vial disclosed by Crankshaw with the aqueous suspension and empty chamber disclosed by Hjertman in order to provide sufficient space for agitation prior to patient administration, as taught by Hjertman.

Hjertman does not specifically disclose that the barrier 13 is a gas impermeable barrier. However, Hjertman discloses the placement of two discrete substances, one including a gaseous medium, in the chambers surrounding the barrier 13. Such a disclosure reasonably suggests to one of ordinary skill in the art that the barrier 13 is made from a gas impermeable material to prevent the gaseous medium in chamber 15 from migrating through the barrier 13 to chamber 6/7. Accordingly, the instantly claimed invention is not patentably distinct from the prior art.

3. Claims 5-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,089,432 to Crankshaw et al in view of US 5,549,561 to Hjertman, further in view of US 6,481,435 to Hochrainer et al.

Crankshaw and Hjertman disclose the device substantially as claimed by applicant (see rejection above) with the exception of the contents and relative formulations of the medicament within the vessel.

Hochrainer discloses that steroids such as, for example, clobetasol and meprednisone, among others, are often packaged in two-chambered dispensing vials in suspensions for administration to a patient in various concentrations (see column 4, lines 5-12, 38-50, columns 5-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the vial disclosed by Crankshaw with a desired medicament for a particular medical treatment, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07, citing *In re Leshin*, 125 USPQ 416. Applicant has not provided any evidence of unexpected results with regard to the storage or use of the particularly claimed medicament compositions. Accordingly, Hochrainer clearly shows the use of medication, as noted above, a person of ordinary skill in the art would recognize that medication having the particular material claimed would be used in the medicament storage and dispensing vial suggested by Crankshaw and Hjertman, absent any showing of such new and unexpected results over the prior art.

Response to Arguments

4. Applicant's arguments filed 29 November 2007 have been fully considered but they are not persuasive.

5. Applicant argues that it would appear unlikely that one with ordinary skill in the art would attempt to modify the Crankshaw reference based on the Hjertman disclosure to provide better storage properties. However, both devices disclosed by the prior art are directed to solving the same problem in the art—maintaining a separation between volatile substances contained in a single device until needed for patient application. As such, the devices are in the same field of endeavor as not only one another, but also as applicant's invention, rendering the devices appropriate for the combination proposed by the Examiner.

6. Applicant further argues that the proposed combination would not arrive at the claimed invention which includes a gas impermeable septum and the contents of the vial. The Examiner notes that she has relied on the Hjertman reference to teach a gas impermeable septum. With regard to Applicant's claimed contents of the vial, it has been held that the recitation of the contents of an apparatus during an intended use of an apparatus is of little significance in determining the patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666 (Bd. App. 1969). In the instant case, applicant is claiming the same structure disclosed by Crankshaw with the addition of a gas-impermeable membrane, which is taught by Hjertmann, and the particular contents of the container. Since the contents of the container are not relevant in determining the

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patentability of the apparatus itself and the gas-impermeable membrane is known in the art as taught by Hjertmann, the apparatus claim is unpatentable over the prior art.

7. Applicant argues that the proposed combination does not provide any headspace in the passage. However, the structure of the vial and stoppers claimed by applicant is illustrated as being identical to the device disclosed by Crankshaw. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Applicant merely claims that the gaseous medium (empty space in the Crankshaw device) performs a specific function. It is the position of the Examiner that since the vial disclosed, claimed, and illustrated by applicant is identical to the vial disclosed by Crankshaw, the vial and empty spaces disclosed and illustrated by Crankshaw is necessarily capable of providing the necessary headspace claimed by applicant. As such, the claimed invention is unpatentable over the prior art of record.

8. Applicant argues that Hjertman teaches away from the instant invention because he discloses that the gaseous medium is soluble in the liquid product. However, Hjertman discloses that the apparatus must provide sufficient space for the liquid product to be mixed with the solid product. As such, Hjertman discloses that during operation, there is sufficient headspace for mixing of the components, and does *not* teach away from the present combination. Additionally, Examiner notes that the Hjertman reference is relied upon to provide the teaching of a gas-impermeable septum, not headspace within the vial.

9. Applicant argues that the Hochrainer reference does not remedy the deficiencies of the Crankshaw and Hjertman combination. However, the Examiner maintains her position that the combination teaches or suggests all the limitations of the claimed invention.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
5 February 2008

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761